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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/392,024 09/08/99 RISER

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EXAMINER

HM22/0428

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ART UNIT

PAPER NUMBER

1644

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DATE MAILED:

04/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/392,024Applicant(s)
Riser et al.Examiner
Karen ClemensGroup Art Unit
1644☐ Responsive to communication(s) filed on _____.☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☐ Claim(s) _____ is/are rejected.☐ Claim(s) _____ is/are objected to.☒ Claims 1-18 are subject to restriction or election requirement.**Application Papers**☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

Drawings have been submitted which fail to comply with 37 C.F.R. § 1.84. Please see the enclosed form PTO-948.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I. Claims 1-3, and 9-11 drawn to a method of treating or preventing a renal disorder wherein the agent is an antibody, classified in Class 424, Subclass 145.1.
- Group II. Claims 1-2, 4, and 9-11 drawn to a method of treating or preventing a renal disorder wherein the agent is an antisense oligonucleotide, classified in Class 514, Subclass 44.
- Group III. Claims 1-2, 5, and 9-11 drawn to a method of treating or preventing a renal disorder wherein the agent is a small molecule, classified in Class 514, Subclass 2, 43.
- Group IV. Claims 1-2, 6, and 9-11 drawn to a method of treating or preventing a renal disorder wherein the agent blocks the CTGF signal transduction pathway, classified in Class 514, Subclass 866.

- Group V. Claims 1-2, 7, and 9-11 drawn to a method of treating or preventing a renal disorder wherein the agent interferes or blocks CTGF post-translational modification, classified in Class 514, Subclass 866.
- Group VI. Claims 1-2, 8, and 9-11 drawn to a method of treating or preventing a renal disorder wherein the agent blocks CTGF precursor activation, classified in Class 514, Subclass 866.
- Group VII. Claim 12, drawn to a method of treating or preventing diabetes comprising administration of insulin and an agent, classified in Class 514, Subclass 866.
- Group VIII. Claim 13, drawn to a pharmaceutical composition, classified in Class 514, Subclass 2, and 43.
- Group IX. Claims 14-18, drawn to a method for diagnosing a renal disorder and the diagnostic kit, Classified in Class 435, Subclass 6, 7.1, and 7.94.

2. The inventions are distinct, each from the other because of the following reasons:

A) Groups VIII and I-VII/IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be practiced with materially different processes. The antibodies and can be used in immunoaffinity purification procedures, the oligonucleotides can be used in polymerase chain reaction assays, the peptides can be used in protein structure analysis, and the macrolides can be used as anti-infective agents. Therefore, they are patentably distinct each from the other.

B) Groups VI-IX and IX are different methods. They require different ingredients, process steps and endpoints to achieve different goals. Therefore, they are patentably distinct each from the other.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

4. Irrespective of whichever Group applicant may elect, applicant is further required under 35 U.S.C. 121:

(I) to elect:

A) a method of treating or preventing or diagnosing a *specific* renal disorder such as diabetes or hypertension if Group I-VI and IX is elected. These disorders are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

B) a method of treating or preventing diabetes administering a *specific* embodiment for the agent if Group VII is elected. These methods of treating or preventing diabetes with the different agents differ with respect to their mode of action and therapeutic endpoints.

C) a pharmaceutical composition with a *specific* embodiment for the agent if Group VIII is elected. These agents differ because they have different physiochemical properties.

(II) to list all Claims readable thereon including those subsequently added. Currently Claims 1-18 are generic.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to Leanne Price on 2/28/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the


application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(l).)

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Clemens whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Karen Clemens, Ph.D.
Patent Examiner
Technology Center 1600
April 24, 2000


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SUPERVISORY PATENT EXAMINER
GROUP 1800-1640